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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,676	06/25/1999	WILLIAM P. VAN ANTWERP	PD-0310	9328

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EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/344,676

Applicant(s)

Van Antwerp

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 7, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Applicants' species elections are acknowledged. However, these species elections are not fully responsive. What is sought is greater specificity with regard to the insulin and the GLP-1. These terms are somewhat ambiguous, and could refer to naturally occurring peptides from any of several mammalian sources, or could refer to various modified peptides. Accordingly, further information is sought. Is the "insulin" and the "GLP-1" that which occurs in humans, or is it from another source, or is it modified in some way?

In addition to the matter of lack of specificity in the elections, responsibility for examination of this application has been transferred from Avis Davenport to the undersigned. Accordingly, a new restriction is imposed.

Claims 26-58 are withdrawn from consideration, pursuant to the first election. (However, in the event that applicants would prefer to pursue one or more of the method claims at this time, rather than composition claims, no objection would be raised thereto).

*

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

G1: Agents (i) and (ii) are required; agent (iii) is permitted but not required;

G2: Agents (i) and (iii) are required; agent (ii) is permitted but not required;

G3: Agents (ii) and (iii) are required; agent (i) is permitted but not required;

G4: The structure of any one (or more) of agents i, ii, and iii cannot be determined without consulting one of the documents that have been incorporated by reference; this would include those agents which are disclosed in USP 5149777; USP 5154646; USP 5753681; and provisional application 60/135278. **G5** is excluded from this subgenus;

G5: The agents can be whatever can be determined from a reading of the specification, taken together with what is known in the art for the amino acid sequences of naturally occurring mammalian C-peptide, insulin, amylin, and IGF-1.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-7, 9-14, 20-23, 25, 59-63, 65-68, 71, limited to G1 and G5.
2. Claims 1-5, 8, 9, 15-17, 20, 24, 59-61, 64, 65, 69 and 71, limited to G2 and G5.
3. Claims 1, 6-9, 15, 18-20, 59, 62-65, 69-71, limited to G3 and G5.
4. Claims 1-7, 9-14, 20-23, 25, 59, 60, 62, 63, 65-68, 71, limited to G1 and G4.
5. Claims 1-5, 8, 9, 15-17, 20, 24, 59-60, 64, 65, 69 and 71, limited to G2 and G4.
6. Claims 1, 6-9, 15, 18-20, 59, 62-65, 69-71, limited to G3 and G4.

The claimed inventions are distinct. First, Groups 1-3 and 4-6 are distinguished. Subgenus G4 has been created because applicants could "extract out" any number of specific genera from the cited references, thereby created new genera that could not have been envisioned from a reading of the specification alone. However, in the event that the elected group is determined to be novel without further amendment, the restriction between Groups 1-3 (on the one hand) and Groups 4-6 would be rendered moot.

Subgenera G1-G3 have been created, because the claims require than only two of the three agents be present. Thus, setting aside the issue of G4 versus G5, there are at least three different inventions. Notwithstanding the foregoing, justification for the restriction is intimately connected with the issue of the degree of novelty of the various inventions. If it is really true that all of the inventions are novel, then rejoining of one or more of the non-elected groups may prove to be appropriate. At the present time, however, this restriction is imposed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

✱

The previous species elections of pioglitazone and Genapol will remain in force, barring any request for new species elections by applicants. As indicated above, identification of a specific "insulin" and "GLP-1" is required, unless applicants choose to elect new species. The elected species should fall within the scope of the elected group; if not, another Office action will be mailed in an attempt to rectify any inconsistency.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention. Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance

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with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "D. Lukton".

DAVID LUKTON
PATENT EXAMINER
GROUP 1800